UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: FRESENIUS GRANUFLO/NATURALYTE DIALYSATE PRODUCTS LIABILITY LITIGATION	MDL No. 1:13-MD-2428-DPW
This Document Relates to:	**REDACTED FILING**
Mervin Boyd, Individually and as Wrongful Death Beneficiary of Judith Boyd, Case No. 1:13-cv-11717-DPW;	LEAVE TO FILE GRANTED ON AUGUST 28, 2017
Daniel Carter, Individually and on Behalf of the Wrongful Death Beneficiaries of Anniece Carter, Case No. 1:13-cv-12459-DPW;	
Joyce Marie Clark, Individually and on Behalf of the Wrongful Death Beneficiaries of Edward Lee Jenkins, Case No. 1:13-cv-12460-DPW;	
Geraldine Dillingham, as Next of Kin and Personal Representative of Estate of Ronnie Dillingham, Case No. 1:15-cv-12796-DPW;	
Gloria Cothern Dunaway, Individually and as Wrongful Death Beneficiary of Betty Sue Cothern, Case No. 1:13-cv-11714-DPW;	
Carlotta Jerry, Individually and as Next of Kin of Christopher Jerry, Case No. 1:15-cv-14121-DPW;	
Alex Kazos, as Next of Kin and Personal Representative of Estate of Nick Kazos, Case No. 1:15-cv-12376-DPW;	
Janice McGhee, Individually and as Wrongful Death Beneficiary of Henry McGhee, Case No. 1:13-cv-13172-DPW;	
Michael McNulty, Individually and as Wrongful Death Beneficiary of Willie Enette McNulty,	

Case No. 1:13-cv-12403-DPW;)
)
Kathleen Palmaccio, as Next of Kin and Personal)
Representative of Estate of John Palmaccio,)
Case No. 1:15-cv-12474-DPW;)
)
Sharon Randall, as Next of Kin and Personal)
Representative of Estate of Winfitch Randall,)
Case No. 1:15-cv-12735-DPW;)
)
Amy Riben, Wife, and Max Riben, Husband,)
And Their Marital Community,)
Case No. 1:15-cv-11134-DPW;)
)
Kimberly Ross, Individually and on Behalf of the)
Wrongful Death Beneficiaries of Stella Ross,)
Case No. 1:13-cv-12478-DPW;)
)
Sophia Walker, Individually and on Behalf of the)
Wrongful Death Beneficiaries of Hattie Myles,)
Case No. 1:13-cv-12487-DPW;)
)
Beulah Williams, on Behalf of the Wrongful)
Death Beneficiaries of Angela Hughes,)
Case No. 1:13-cv-12486-DPW;)
)
Angelos Zachery, et al., Individually and as)
Executor of the Estate of Nellie Fredrick)
McClendon,)
Case No. 1:14-cv-13150-DPW)
_____)

MEMORANDUM IN SUPPORT OF FMCNA'S MOTION FOR SUMMARY JUDGMENT ON THE CLAIMS OF OPT-OUT CASES LACKING EVIDENCE OF ELEVATED SERUM BICARBONATE LEVELS

Pursuant to Federal Rule of Civil Procedure 56, Defendants, Fresenius Medical Care Holdings, Inc., Fresenius USA, Inc., Fresenius USA Manufacturing, Inc., and Fresenius USA Marketing, Inc. (collectively "FMCNA") submit this memorandum in support of their motion for summary judgment on the claims of all opt-out plaintiffs who lack evidence of elevated serum bicarbonate levels and whose injuries thus cannot have been caused by FMCNA. To date, FMCNA has identified the following 16 opt-out plaintiffs who are subject to this motion: Mervin Boyd (Judith Boyd); Daniel Carter (Anniece Carter); Joyce Marie Clark (Edward Lee Jenkins); Geraldine Dillingham (Ronnie Dillingham); Gloria Cothern Dunaway (Betty Sue Cothern); Carlotta Jerry (Christopher Jerry); Alex Kazos (Nick Kazos); Janice McGhee (Henry McGhee); Michael McNulty (Willie Enette McNulty); Kathleen Palmaccio (John Palmaccio); Sharon Randall (Winfitch Randall); Max Riben (Amy Riben); Kimberly Ross (Stella Ross); Sophia Walker (Hattie Myles); Beulah Williams (Angela Hughes); and Angelos Zachery (Nellie Fredrick McClendon).[1]

I. INTRODUCTION

While certainly not sufficient by itself to make a triable case, proof that a patient had a high pre-dialysis serum bicarbonate level preceding a cardiac arrest is a necessary ingredient to Plaintiffs' theory of liability. Plaintiffs allege that GranuFlo® and NaturaLyte® increase patients' serum bicarbonate levels, elevated serum bicarbonate is dangerous because it allegedly leads to alkalosis and cardiac arrest, and FMCNA failed to warn physicians about these alleged risks so they could adjust their prescriptions. By its terms, Plaintiffs' theory of causation is

[1] As explained in FMCNA's brief in support of its motion for summary judgment regarding NaturaLyte® opt-out cases, filed on August 23, 2017 (Doc. 1907, at p. 1), FMCNA has identified multiple grounds for dispositive motions in the 20 opt-out cases. Many of the cases are subject to dismissal on more than one ground. For example, 8 of the plaintiffs identified in this motion also are subject to the NaturaLyte® motion (Doc. 1906).

contingent on the patient having elevated serum bicarbonate. Patients who do not meet this criterion do not have viable claims.

Critically, the Hakim Memo – the centerpiece of Plaintiffs' complaint – purports to find a statistically significant increased risk of cardiopulmonary arrest only for patients who had elevated pre-dialysis serum bicarbonate levels. Although the memo does not define what constitutes an "elevated" level, the data draws the line at a serum bicarbonate reading of 28 mEq/L or above. Indeed, the Hakim Memo data depicts patients with a serum bicarbonate below 28 and potassium of 4 or greater as having no increased risk. Thus, in any opt-out case in which the patient's lab values were within the range that even Dr. Hakim depicted as safe, the chain of events Plaintiffs describe (high serum bicarbonate triggering alkalosis triggering cardiac arrest) cannot have occurred. As there can be no causal connection between the alleged injury and GranuFlo® or NaturaLyte® in such cases, FMCNA is entitled to summary judgment.

In addition, Plaintiffs' own nephrology experts admit that a doctor would not be expected to change a bicarbonate prescription when the patient's lab values are within the target range. They further have acknowledged that a lab value up to 26 is within a reasonable target for serum bicarbonate, and patients whose last serum bicarbonate level did not exceed that threshold did not need a downward adjustment to their prescribed bicarbonate setting. Thus, regardless of the information their physicians did or did not receive from FMCNA about GranuFlo® and NaturaLyte®, any alleged failure to warn was not the proximate cause of the claimed injury when the patient's last pre-dialysis serum bicarbonate value was 26 or lower. Accordingly, FMCNA is entitled to summary judgment for this additional reason in any opt-out case within this category.

II. UNDISPUTED MATERIAL FACTS

A. Plaintiffs' Theory

The gravamen of Plaintiffs' complaint in this litigation is that FMCNA failed to warn physicians about how to use GranuFlo® and NaturaLyte® safely with their hemodialysis patients. See, e.g., 2d Amended Master Compl. ¶¶ 1-3, 110, 113, 126-127, 158, 168-169, 177, 182, 211, 217-218, 227-229 (Doc. 1232). Plaintiffs allege that GranuFlo® and NaturaLyte® contain acetate, which they claim leads "to a dangerous increase in serum bicarbonate levels in patients undergoing hemodialysis," allegedly resulting in metabolic alkalosis, which in turn triggers cardiac arrest and sudden cardiac death. Id. at ¶ 115; see also id. at ¶ 217.

Plaintiffs' theory of causation is focused on high – not mid-range or low – serum bicarbonate levels. Plaintiffs allege that "[a]lkalosis is caused by too much bicarbonate in the blood." 2d Amended Master Compl. ¶ 82 (emphasis added); see also id. at ¶ 113 ("Patients with elevated bicarbonate levels in their blood suffer from metabolic alkalosis, … and high bicarbonate levels in the blood increases a patient's risk of cardiopulmonary ("CP") or sudden cardiac arrest.") (emphasis added). They allege that "increased bicarbonate levels can adversely affect the heart." Id. at ¶¶ 121-27. They assert that "high serum bicarbonate levels increases the patients' risk of mortality." Id. at ¶ 185. They claim that doctors should have been advised to "pay attention to the increase in serum bicarbonate levels as a result of the use of" GranuFlo® and NaturaLyte®. Id. at ¶ 182. They allege that FMCNA should have warned doctors "to reduce the amount of bicarbonates being delivered to the patient during dialysis to take into account the additional bicarbonate from NaturaLyte and/or GranuFlo." Id. at ¶ 169.

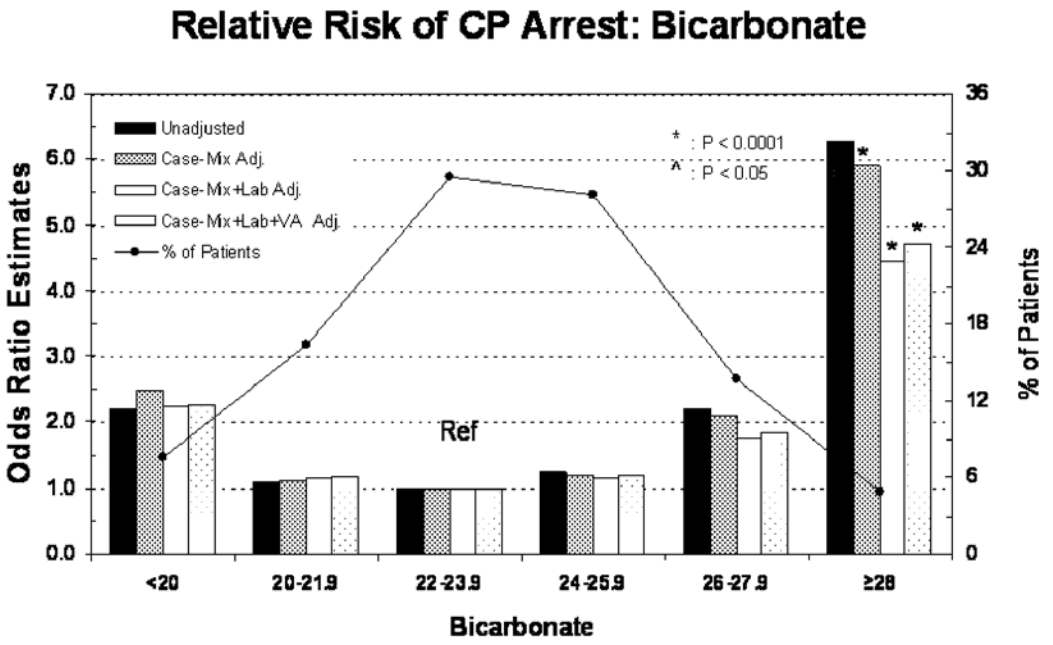
Although the Second Amended Master Complaint does not purport to define what constitutes a "high" serum bicarbonate level, it does not allege that there are any increased risks associated with levels below 24. See 2d Amended Master Compl. ¶¶ 172, 184. To the extent it

refers to studies or data reviews, they are overwhelmingly focused on bicarbonate levels of 28 or greater. Id. at ¶¶ 173, 184, 199, 209-210. This includes the Hakim Memo that inspired this litigation, as discussed next.

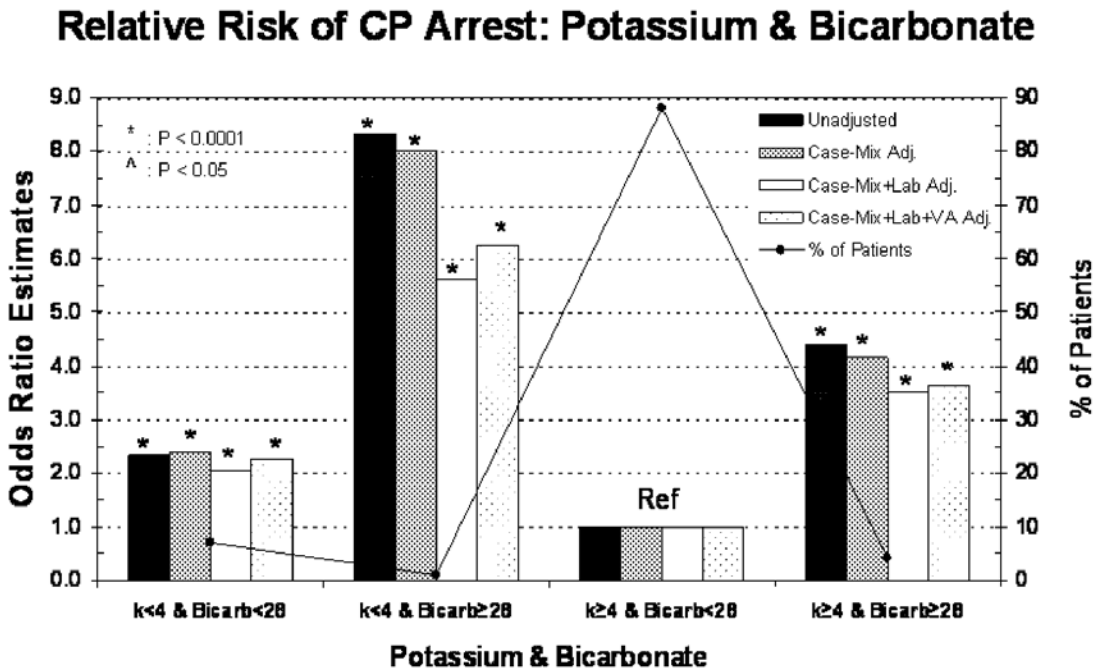
B. The Hakim Memo

The genesis of this litigation, and the centerpiece of Plaintiffs' complaint, is the November 4, 2011, memorandum written by Dr. Hakim on "Dialysate Bicarbonate, Alkalosis and Patient Safety." See 2d Amended Master Compl. ¶¶ 208-211 (Doc. 1232). In that memo, Dr. Hakim reviewed data pertaining to 941 patients who experienced cardiopulmonary arrest during dialysis at FMCNA clinics, divided patients into different buckets based on their last reported pre-dialysis lab values, and attempted to identify their risk for experiencing such an event. SOF ¶¶ 1-4; Ex. 1. Although Dr. Hakim made sweeping conclusions and commentary (which have been excluded from evidence as junk science) about what he perceived as a need to adjust bicarbonate prescriptions downward across the board when GranuFlo® and NaturaLyte® were used, the data as depicted in figures 2 and 3 in the memo showed no statistically significant increased risk for patients with bicarbonate levels in the mid- to low 20s. SOF ¶¶ 3-7; Ex. 1.

As set forth in figure 2 in the Hakim Memo, when focusing on bicarbonate alone, patients with a pre-dialysis serum bicarbonate level of 28 or greater were depicted as having the greatest relative risk for cardiopulmonary arrest during dialysis as compared to other groups. No other group was denoted as having a statistically significant increased risk (as indicated by an * or ∧). See SOF ¶¶ 3, 5-6; Ex. 1.



As set forth in figure 3, when potassium lab values were included in the analysis, patients with a last serum bicarbonate value under 28 and potassium greater than or equal to 4 had no increased risk, even under Dr. Hakim's analysis (as depicted in the bars labeled "Ref" for reference range). See SOF ¶¶ 4-5, 7; Ex. 1.



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C. Plaintiffs' Nephrology Expert Evidence

Plaintiffs designated multiple nephrologists as expert witnesses in this litigation, and these doctors have offered opinions about what is a "high" pre-dialysis serum bicarbonate level and what levels would prompt them to adjust prescriptions for their own patients. Although they debate what the ideal or perfect serum bicarbonate level is, a consensus has emerged that pre-dialysis serum bicarbonate levels of 26 or lower are not generally a cause for a downward prescription change of the sort Plaintiffs claim FMCNA should have advised physicians to make.

1. Dr. Derek Fine

Plaintiffs' expert Dr. Fine is an Associate Professor of Medicine at Johns Hopkins University School of Medicine and has a clinical practice that includes treating dialysis patients at a DaVita outpatient dialysis unit in Baltimore, Maryland. SOF ¶ 9. At his deposition, Dr. Fine was asked what he considers a "normal" range for pre-dialysis serum bicarbonate. SOF ¶ 10. Dr. Fine responded that there are "varying opinion[s]," but "if I'm talking to my nurse practitioners or my fellows and I'm teaching them, I'd say I'd like to see the bicarb somewhere between, in most cases, 20 and 24…. I would tell them that K/DOQI guidelines say greater than 22 is a reasonable target." Id. Dr. Fine further explained that nurse practitioners "usually want you to give them … a number that you want [them] to worry about" and, for him, that number is "something above 26." SOF ¶ 11. Dr. Fine testified he also would be interested in large swings in a patient's serum bicarbonate over a short period of time, giving an example of a patient moving from 18 to 25 in a week. Id. If he could place an "upper limit" for pre-dialysis serum bicarbonate in the KDOQI guidelines, he would set it at 27. SOF ¶ 12.

Dr. Fine further testified that, unless a patient is "alkalotic," he does not believe there is a need to individualize the prescription and adjust the machine bicarbonate setting downward. SOF ¶ 13. Dr. Fine uses a standard prescribed bicarbonate setting of 35 at his clinic. SOF ¶ 14. At the time of his deposition, all of his patients at the clinic were on that standard prescription, and he was not aware of any that had been adjusted in the past year. Id.

2. Dr. Sushrut Waikar

Plaintiffs' expert Dr. Waikar is an Associate Professor of Medicine at Harvard Medical School and also treats nephrology patients, including some who are on dialysis, at Brigham & Women's Hospital in Boston. SOF ¶ 17. Dr. Waikar testified that the "typical serum bicarbonate range is around 20 to 26." SOF ¶ 18. When asked if there was a range he targeted for his own patients' pre-dialysis serum bicarbonate levels, Dr. Waikar responded, "22 to 26, around there, would be reasonable, maybe 22 to 24." Id.

Dr. Waikar also testified about the circumstances that would lead him to adjust the bicarbonate prescription for a patient, which include "[t]he presence or absence of chronic obstructive pulmonary disease, the presence or absence of severe metabolic alkalosis or acidosis." SOF ¶ 19. When asked to explain what he meant when he referred to a patient presenting with metabolic alkalosis, Dr. Waikar gave an example of a patient who "comes into the dialysis unit and the serum bicarbonate concentration is 35." Id. He gave similar examples of a patient with a serum bicarbonate level of 30 or 35 when asked what he meant when he referred to "significant alkalosis." Id.

3. Dr. David Goldfarb

Plaintiffs' expert Dr. Goldfarb is a professor at New York University and treats dialysis

patients at a VA unit in the New York Harbor Healthcare System. SOF ¶ 20. In discussing bicarbonate levels that would be a potential cause for concern for a patient, Dr. Goldfarb gave "28 or 30 or 35" as examples, in addition to levels below 22. SOF ¶ 21. He testified that he is "concerned about the individuals at the extremes." Id.

All of Dr. Goldfarb's dialysis patients in the outpatient setting are on a standard prescription of 35 for their bicarbonate setting with an acid concentrate that contains 4 mEq/L of acetate. SOF ¶ 22. He does not ever adjust his patients' prescriptions based on their lab values for serum bicarbonate. SOF ¶ 23. He would not advise his colleagues to change the bicarbonate prescriptions for their dialysis patients downward or upward. Id.

4. Dr. Steven Borkan

Finally, Dr. Borkan offered generic and case-specific opinions on behalf of Plaintiffs, including at trial in the Dial case. He is a professor at Boston University and also maintains a clinical nephrology practice in facilities affiliated with DaVita. SOF ¶ 24. Dr. Borkan testified that his "target" pre-dialysis serum bicarbonate range for his own patients is between 22 and 24 mEq/L. SOF ¶¶ 25, 27.

While Dr. Borkan identified 22-24 as his personal "target" range, he did not testify that slightly higher levels up to 26 are dangerous or require an adjustment to the prescribed machine setting.

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D. Last Lab Values of Plaintiffs or Their Decedents

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III. LEGAL STANDARD FOR SUMMARY JUDGMENT

"Summary judgment is appropriate when 'the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.'" Pagano v. Frank, 983 F.2d 343, 347 (1st Cir. 1993) (quoting Fed. R. Civ. P. 56(c)). When a defendant moves for summary judgment based on a lack of evidence supporting the plaintiffs' claim, "the plaintiff must establish the existence of a triable issue which is both genuine and material to his claim." Id. Plaintiffs "must present definite, competent evidence to rebut the motion" and cannot merely rest on "conclusory allegations, improbable inferences, and unsupported speculation." Id. (quotation marks and citations omitted). If the plaintiffs' theory of liability is unsupported, summary judgment should be entered in favor of the defendant. See, e.g., Geshke v. Crocs, 740 F.3d 74, 77 (1st Cir. 2014); see also Koken v. Black & Veatch Constr., 426 F.3d 39, 49 (1st Cir. 2005) ("When there is so little evidence tending to show a critical element of a plaintiff's claim that the jury would have to speculate in order to return a verdict for the plaintiff, a defendant is entitled to summary judgment.").

IV. ARGUMENT

A. Patients with Bicarbonate Levels Below 28 Are Outside the Hakim Memo Risk Range and Thus Lack Evidence of Medical Causation.

Under any substantive law relevant to this motion, causation is an essential element of

Plaintiffs' product liability claims. See In re Norplant Contraceptive Prods. Liab. Litig., 215 F. Supp. 2d 795, 830 (E.D. Tex. 2002) (noting "[t]he causation requirements in failure to warn claims are similar in all United States jurisdictions"); In re Mirena IUD Prods. Liab. Litig., 202 F. Supp. 3d 304, 310 (S.D.N.Y. 2016) ("As in any products liability or personal injury action, Plaintiffs must prove causation."). To prove causation in a mass tort products liability action, Plaintiffs must proffer evidence of both (1) general causation – that is, that GranuFlo® and NaturaLyte® are capable of causing their alleged injuries; and (2) specific causation – that GranuFlo® or NaturaLyte® did, in fact, cause the injury in each individual case. Id.; see also, e.g., In re Neurontin Marketing, Sales Practices, & Prods. Liab. Litig., 612 F. Supp. 2d 116, 123 (D. Mass. 2009); In re Zoloft Prods. Liab. Litig., 176 F. Supp. 3d 483, 491 (E.D. Pa. 2016); In re Breast Implant Litig., 11 F. Supp. 2d 1217, 1224 (D. Colo. 1998) (citing cases from many jurisdictions). A defendant such as FMCNA can demonstrate that there is no genuine issue of material fact as to causation by showing an absence of evidence concerning general causation. In re Norplant, 215 F. Supp. 2d at 830.

The data discussed in the Hakim Memo is the foundation for Plaintiffs' general causation theory that GranuFlo® and NaturaLyte® increase patients' serum bicarbonate to "dangerous" levels triggering alkalosis and cardiac arrest. All of their nephrology experts rely on it. SOF ¶¶ 32-38. As depicted in the Memo, however, the purported heightened risk of cardiopulmonary arrest applies only to patients whose last pre-dialysis lab results fall in certain buckets – specifically, serum bicarbonate of 28 or greater, or, when analyzed with potassium, any serum bicarbonate level combined with potassium of less than 4. Under Dr. Hakim's own data review, patients whose last pre-dialysis lab for serum bicarbonate was below 28 were depicted in figure 2

as having a markedly lower risk for cardiopulmonary arrest during dialysis. Ex. 1, p. 3.[4] Further, in figure 3, a patient whose last pre-dialysis serum bicarbonate reading was under 28 and whose potassium was 4 or greater was within Dr. Hakim's "reference range" – the lowest risk group that set the baseline against which all others were compared. Ex. 1, p. 4.

Plaintiffs' theory of general causation simply does not apply to patients who lack an elevated serum bicarbonate level, and FMCNA is entitled to summary judgment on their claims. Cf. Wells v. SmithKline Beecham Corp., 2009 WL 564303, at *6 (W.D. Tex. Feb. 18, 2009) (a plaintiff cannot establish specific causation if he or she is not "similarly situated to the participants" in any epidemiological studies used to demonstrate general causation), aff'd, 601 F.3d 375 (5th Cir. 2010).

Plaintiffs have no competent evidence that would support expanding their claims beyond the patient groups the Hakim Memo data depicts as subject to heightened risk of cardiac arrest,

[4] While figure 2 of the Hakim Memo depicts patients with a pre-dialysis serum bicarbonate level under 20 and those between 26 and 27.9 as having a higher relative risk than patients with pre-dialysis serum bicarbonate between 20 and 25.9, the only group with bars that are marked as statistically significant (with an * or ^) is patients with serum bicarbonate levels of 28 or greater.

that is, those with pre-dialysis serum bicarbonate levels of 28 or greater. In a medical drug or device products liability case, evidence of general causation must be established through expert testimony. In re Zoloft, 176 F. Supp. 3d at 491; In re Mirena, 202 F. Supp. 3d at 311; In re Norplant, 215 F. Supp. 2d at 830. Plaintiffs' nephrology experts conducted no independent studies on the alleged association between serum bicarbonate levels and the risk of cardiac arrest. See SOF ¶¶ 34, 36, 38. Although in some instances they attempt to bolster their conclusions by discussing other research and data in addition to the Hakim Memo, the peer-reviewed published research concludes that any association between serum bicarbonate levels and poor dialysis outcomes is a consequence of the unfortunate fact that as dialysis patients become sicker and near death, they tend to eat less, develop infections, and fall subject to a number of other disease processes that increase serum bicarbonate levels.[5] These processes and increase in serum

[5] See, e.g., SOF ¶ 39; Ex. 13 (Wu, Association between Serum Bicarbonate and Death in Hemodialysis Patients: Is It Better to Be Acidotic or Alkalotic? (2006)) ("The lowest **unadjusted** mortality was associated with predialysis HCO3- [bicarbonate] in the 17- to 23-mEq/L range, whereas values ≥23 mEq/L were associated with progressively higher all-cause and cardiovascular death rates. This association, however, **reversed** after case-mix and MICS multivariate adjustment, so that HCO3- values >22 mEq/L had lower death risk. Although previous epidemiologic studies indicated an association between high serum HCO3- and increased mortality in MHD [maintenance hemodialysis] patients, this effect seems to be due substantially to the effect of MICS [malnutrition-inflammation complex syndrome] on survival.") (emphasis added).

SOF ¶ 40; Ex. 14 (Tentori, Association of Dialysate Bicarbonate Concentration Mortality in the Dialysis Outcomes and Practice Patterns Study (DOPPS) (2013)) ("In the present analysis, **serum bicarbonate levels >23 mEq/L were not associated with increased mortality**. … Our findings are in agreement with results from a more recent analysis that reported no association between serum bicarbonate level >22 mEq/L and mortality after adjustment for nutritional and inflammatory markers.") (emphasis added).

SOF ¶ 41; Ex. 15 (Yamamoto, Predialysis and Postdialysis pH and Bicarbonate and Risk of All Cause and Cardiovascular Mortality in Long–term Hemodialysis Patients (2015) ("[P]re- and postdialysis bicarbonate levels were not associated with all-cause and CV mortality.").

SOF ¶ 42; Ex. 16 (Gennari, Very Low and High Predialysis Serum Bicarbonate Levels are Risk Factors for Mortality: What are the Appropriate Interventions? (2010)) ("After adjusting for all

bicarbonate levels have nothing to do with the presence of acetate in the dialysate. The ultimate conclusions of Plaintiffs' relevant experts on general causation are tethered to the Hakim Memo data and are subject to its limitations. See SOF ¶¶ 32-38. Absent competent expert evidence that GranuFlo® and NaturaLyte® can cause cardiac arrest in patients whose serum bicarbonate levels were not elevated – that is, below 28 – prior to dialysis, there is no showing of general causation as to those patients, and FMCNA is entitled to summary judgment.

Similar to this case, the In re Norplant litigation was a multidistrict products liability proceeding involving allegations of failure to warn related to a prescription birth control device. After the parties reached a settlement and most plaintiffs chose to participate, the court addressed summary judgment motions directed to the claims of the remaining plaintiffs from a number of different states. As to plaintiffs who complained of "exotic conditions" allegedly related to the device, and not the 26 side effects at issue in the core liability theory, the court dismissed their claims on summary judgment as scientifically baseless. 215 F. Supp. 2d at 829. The court found that the plaintiffs failed to produce "a shred of evidence or expert testimony that supports an association between Norplant and any of the exotic conditions" and granted summary judgment dismissing those claims on the ground that there was no scientifically reliable evidence of general causation. Id. at 833. Likewise here, claims involving patients whose last pre-dialysis serum bicarbonate level was below 28 fall outside the scope of the core liability theory in the case and are not supported by the requisite evidence of general causation. Because Plaintiffs have not adduced evidence that GranuFlo® or NaturaLyte® is generally capable of causing

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these factors, the increase in mortality with high levels of [HCO3] **virtually disappeared**, save for values > 27 mmol/l, and mortality increased with low values. … These data are essentially in agreement with the DOPPS study and again suggest that management of patients with unusually high predialysis serum [HCO3] should be directed at management of malnutrition and comorbidity rather than at treating the [HCO3] itself.").

cardiac arrest in a patient who does not have elevated pre-dialysis serum bicarbonate levels, FMCNA is entitled to summary judgment.

B. In Addition, Plaintiffs' Own Experts' Testimony Shows FMCNA's Alleged Failure to Warn Could Not Proximately Cause Injury to Patients with Bicarbonate Levels of 26 or Lower.

For patients whose last pre-dialysis serum bicarbonate labs were 26 or lower, summary judgment is warranted for the additional reason that Plaintiffs' own experts have acknowledged that a physician would not be expected to make any downward adjustment to the bicarbonate setting. Thus, there is no proximate causation linking the alleged failure to warn to the alleged injury in these patients.

To prevail on a failure to warn claim under any applicable law, in each case Plaintiffs must show that the doctor would have done something differently if he or she had received the warning they claim should have been given. See, e.g., Bock v. Novartis Pharmaceuticals, 137 F. Supp. 3d 802, 808 (W.D. Penn. 2015), aff'd, 661 F. App'x 227, 232 (3d Cir. 2016); In re Neurontin Marketing & Sales Practice & Prods. Litig., 2010 WL 3169485, at *4 (D. Mass. Aug. 10, 2010); Cross v. Forest Labs., 102 F. Supp. 3d 896, 902-06 (N.D. Miss. 2015); Ingram v. Novartis Pharmaceuticals, 888 F. Supp. 2d 1241, 1244-47 (W.D. Okla. 2012); Small v. Amgen, 134 F. Supp. 3d 1358, 1371-72 (M.D. Fla. 2015); Dietz v. Smithkline Beecham, 598 F.3d 812, 816 (11th Cir. 2010) (Georgia law); Lovick v. Wil-Rich, 588 N.W.2d 688, 700 (Iowa 1999); Willett v. Baxter Int'l, Inc., 929 F.2d 1094, 1098–99 (5th Cir. 1991) (Louisiana law). Without such evidence, there is no basis to conclude that the alleged failure to warn caused their injury. See Wheat v. Pfizer, 31 F.3d 340, 343 (5th Cir. 1994) (To prevail on a failure-to-warn claim, Plaintiffs have to show proximate cause, which means that "a proper warning would have changed the decision of the treating physician."); In re Norplant, 215 F. Supp. 2d at 828

(addressing failure to warn claims in multi-state mass tort litigation and granting summary judgment to defendants when plaintiffs failed to show a different warning would have changed the decision of physicians who prescribed drug to plaintiffs).

Plaintiffs cannot show any failure to warn caused injury for patients whose last pre-dialysis serum bicarbonate reading was 26 or lower, because Plaintiffs' own experts acknowledge that on-target lab results do not require any prescription change. For example, in describing the target range for his own patients, Dr. Waikar acknowledged that 22 to 26 is "reasonable." SOF ¶ 18. Dr. Goldfarb takes notice of serum bicarbonate levels of "28 or 30 or 35" and below 22. SOF ¶ 21. A lab reading above 26 is the threshold Dr. Fine gives his nurse practitioners for when he wants to be notified. SOF ¶ 11. Dr. Fine further opined that it is unnecessary to adjust the bicarbonate prescription downward unless the patient is "alkalotic." SOF ¶ 13. While Dr. Fine also indicated he would consider making adjustments if a patient's serum bicarbonate levels had drastic upward swings in a short period of time, there is no evidence any patients in the cases at issue here had such swings in their monthly labs. See p. 10 above.

For all of these patients, whether their nephrologist knew everything or nothing about GranuFlo® and NaturaLyte®, acetate, acid-base balance, and related subjects, the nephrologist would not be expected to "dial down" the bicarbonate prescription in response to such values. Thus, FMCNA's alleged failure to warn cannot be the proximate cause of the claimed injuries.

In sum, because Plaintiffs' own experts have admitted that a pre-dialysis serum bicarbonate lab result of 26 or less does not require a downward adjustment in the prescription, Plaintiffs have no failure-to-warn claim in any case where the patient's last lab did not pass that threshold. For this additional reason, summary judgment should be granted in favor of FMCNA in all opt-out cases where the patient's last pre-dialysis serum bicarbonate lab value was 26 or lower.

Dated: August 28, 2017

Respectfully submitted,

/s/ James F. Bennett

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CERTIFICATION OF SERVICE

I hereby certify that a true and correct copy of the foregoing document was served on Plaintiffs' counsel by e-mail on August 28, 2017, to:

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